EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRIAN JOSEPH GREF,

Plaintiff,

v.

AMERICAN INTERNATIONAL INDUSTRIES, *et al.*,

Defendant.

No. 1:20-cv-005589-GBD

MEMORANDUM IN SUPPORT OF NON-PARTY NORTHWELL HEALTH, INC.'S MOTION TO MODIFY SUBPOENA SERVED BY DEFENDANT AMERICAN INTERNATIONAL INDUSTRIES

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Pursuant to Rule 45(d)(3) of the Federal Rules of Civil Procedure, non-party Northwell Health, Inc. ("Northwell") by and through its undersigned counsel, hereby moves the Court for an Order modifying Defendant American International Industries' ("AII") Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (the "Subpoena"), so as to enjoin AII from compelling Northwell to identify any research subjects or produce documentation from which the identities of such subjects can be ascertained. As explained in detail below, the disclosure of such information would be contrary to:

1. The Federal Policy for the Protection of Human Subjects, 45 C.F.R. Part 46, Subpart A ("The Common Rule");

2. Bedrock Institutional Review Board ("IRB") standards of privacy and confidentiality covering research subjects;

3. The specific IRB approvals that Dr. Moline secured in advance of writing and publishing her peer-reviewed article entitled "Mesothelioma Associated with the Use of Cosmetic Talc;"

4. Well-established standards and universally accepted norms in the medical research community related to research subjects and anonymity; and

5. Relevant case law affirming privacy and confidentiality requirements for research subjects.

In addition, preserving the anonymity of research subjects is essential to avoid the chilling effect that disclosure of those subjects' identities would inevitably have on their willingness to participate in future research studies (as well as on the willingness of other potential subjects to participate in future research studies). Accordingly, Northwell requests the Court grant its Motion.

I. BACKGROUND

Northwell is the largest health care system (and the largest private employer) in the State of New York, with 21 hospitals and more than 850 outpatient facilities. It is home to the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell, the Hofstra Northwell School of

Nursing, the Elmezzi Graduate School of Molecular Medicine, and various other academic and research programs. Northwell employs more than 80,000 people, and boasts approximately 12,000 credentialed physicians—including 4,900 employed doctors—as well as 18,900 nurses and more than 5,000 volunteers. In 2022, Northwell reported over 5.5 million patient encounters, including 259,378 hospital discharges, over 825,000 emergency visits, over 4 million home health visits, 225,000 ambulatory surgeries, and 108,857 ambulance transports. In 2022, Northwell contributed more than $1.4 billion in community benefit (12.7% of operating expenses) by participating in more than 13,000 community health programs and training 39,000 health professionals.

Northwell employs Dr. Jacqueline Moline, a physician who is board-certified in internal and occupational medicine. Huff Aff., Ex. F (Moline Aff. at ¶ 2).[1] In addition to other roles, Dr. Moline is the chairperson of the Department of Occupational Medicine, Epidemiology and Prevention at North Shore University Hospital, one of Northwell's affiliate hospitals. *Id.* at ¶ 3. Dr. Moline is also a professor of medicine at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell. *Id.* at ¶ 4. She serves on the editorial boards of several journals on industrial, occupational and environmental medicine, and is a fellow of the American College of Physicians, the American College of Occupational and Environmental Medicine, and the New York Academy of Medicine. *Id.* at ¶¶ 5-6.

In 2019, Dr. Moline—along with Kristin Bevilacqua, MPH, Maya Alexandri, JD, and Ronald Gordon, Ph.D.—authored and published a peer-reviewed article entitled, "Mesothelioma Associated with the Use of Cosmetic Talc" (the "Article"). *Id.* at ¶ 7. The Article was based on

[1] Northwell notes that Dr. Moline's affidavit was provided in another case (and reflects the caption of that case). Because Northwell relies on the same facts and testimony provided therein, Northwell does not believe a new, identical affidavit is necessary here.

the authors' analysis of certain records associated with 33 individuals with malignant mesothelioma who reportedly had no known asbestos exposure other than to cosmetic talcum powder. *Id.* at ¶ 8. The Article concludes that exposure to asbestos-contaminated talcum powders can cause mesothelioma and that clinicians should elicit a history of talcum powder usage in all patients presenting with mesothelioma. *Id.* at ¶ 9.

Prior to drafting the Article, Dr. Moline sought and secured approval from Northwell's Human Research Protection Program ("HRPP") through its Institutional Review Board ("IRB"). *Id.* at ¶ 10. Northwell's HRPP supports, facilitates, and promotes the ethical and safe conduct of research involving human subjects at Northwell. *Id.* at ¶ 11. The Northwell IRB is an independent research ethics review board—mandated by law and applicable regulations—and consists of healthcare professionals, scientists, and local community members. *Id.* at ¶ 12. The IRB serves to protect research participants' rights and welfare before and during research studies. *Id.* at ¶ 14. Specifically, IRBs are intended to ensure the protection of research subjects' privacy and confidentiality rights, including—most fundamentally—their identities and protected health information ("PHI"). *Id.* at ¶ 15.

In her application for approval from the Northwell IRB for the research study and publication of the Article, Dr. Moline represented that: (1) she took confidentiality seriously and would take extensive measures to protect the participants' identities; (2) no patient identifiers would be included in research-related summaries; (3) all PHI included in her review and the Article would be de-identified; and (4) the PHI would be stored in Northwell's secure database. *Id.* at ¶ 16. As a result of these and other representations about the research study, Northwell's IRB granted approval on March 23, 2018. *Id.* at ¶ 17. In so doing, the IRB approval stated that Dr. Moline's research study met the criteria outlined in 45 C.F.R. § 46.110 and 21 C.F.R. § 56.110,

which relate to expedited review and are part of regulations that stringently require research subject privacy and confidentiality. *Id.* at ¶¶ 18-19. Indeed, the IRB approval was specifically premised on the fact that Dr. Moline's research study contained adequate safeguards to protect and maintain the confidentiality of data and research participants. *Id.* at ¶ 19. The IRB approval also specified that Dr. Moline's research must be conducted in accordance with, *inter alia*, 45 C.F.R. § 46 and the Health Insurance Portability and Accountability Act ("HIPAA"). *Id.* at ¶ 20.

Following the IRB's approval in March 2018 and throughout the Article's research and publication process, Dr. Moline protected the research subjects' privacy and confidentiality. *Id.* at ¶ 21. Specifically, she did not disclose or otherwise reveal the research subjects' identities, as required by Northwell's IRB and applicable laws and regulations. *Id.* at ¶ 22. Indeed, to date, Dr. Moline has not voluntarily disclosed the identities of the research subjects in the Article. For example, when she was deposed in a separate but related federal case in January 2020, *Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C.), Dr. Moline refused to confirm or deny the plaintiff's identity as a research subject in response to questions from counsel for Defendant AII about the Article. *Id.* at ¶ 23. Dr. Moline's refusal to identify the plaintiff's status as a research subject was based on IRB, privacy, and confidentiality standards surrounding research studies. *Id.* at ¶ 24. Ultimately, the *Bell* court protected the anonymity of all 33 research subjects with the exception of the plaintiff, and made that exception primarily because (1) she was a party to the litigation and had thus placed her identity as a research subject—along with other information—squarely within the realm of discoverability, and (2) she no longer qualified as a "human subject" under 45 C.F.R. § 46.111(a)(7) given that she had passed during the pendency of the litigation (and before Dr. Moline co-authored the Article). Huff Aff., Ex. C (Memorandum Opinion and Order, *Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C.)). Dr. Moline also refused to identify the 33 research

subjects at trial in *Johnson/Lashley v. Am. Int'l Indus.*, Nos. MID-L-006651-16ASL and MID-L-007336-16AS (N.J. Super. Ct. Law Div.). Huff Aff., Ex. D (Trial Transcript at 205-07, *Johnson/Lashley v. Am. Int'l Indus.*, Nos. MID-L-006651-16ASL and MID-L-007336-16AS (N.J. Super. Ct. Law Div.)). In that case, while the court allowed AII to cross-examine Dr. Moline regarding her study methodology, it held that identification of a study subject would be inappropriate, even where AII was attempting to match the identity of a subject to a plaintiff in a case in which AII was a named defendant. *Id.* at 217-20. Likewise, in a recent state court case in Pennsylvania, *Fisher v. Am. Int'l Indus.*, No. 19070087 (Pa. D.&C.), Dr. Moline refused at trial to provide testimony that would identify any of the 33 research subjects. Huff Aff., Ex. E (Trial Transcript at 31-32, 39-40, *Fisher v. Am. Int'l Indus.*, No. 19070087 (Pa. D.&C.)). The *Fisher* court refused to compel Dr. Moline to identify any of the 33 research subjects. *Id.* at 40.

On or about September 27, 2022, counsel for AII served Northwell with a Rule 45 subpoena requesting a range of documents related to Dr. Moline including, *inter alia*, information surrounding the Article. *See* Huff Aff., ¶ 6. While the response date on the subpoena was listed as October 18, 2022, AII and Northwell mutually agreed to extend the time for response until November 4, 2022.[2] *Id.* at ¶ 8.

Pursuant to The Common Rule, bedrock and widely accepted IRB requirements of confidentiality and privacy, and applicable case law, it would be improper for Northwell to identify the research subjects on which Dr. Moline's Article is based or to produce documentation from which the identity of research subjects can be identified. Moreover, because Northwell is a

[2] Separate from the instant Motion, on October 12, 2022, Northwell served its Objections to Subpoena. To the extent the Subpoena is non-objectionable, Northwell intends to make a production of documents responsive to the Subpoena contemporaneously with the filing of this Motion.

"covered entity" under the Health Insurance Portability and Accountability Act ("HIPAA"), and because de-identifying research subjects would divulge their protected health information ("PHI")—namely, that they have mesothelioma—it would be improper for Northwell to identify the research subjects under HIPAA. Consequently, Northwell respectfully requests that the Court modify AII's Subpoena to protect the confidentiality to which its research subjects—including those Dr. Moline studied in writing her Article—are entitled. Specifically, Northwell requests that the Court enter an order which:

- Orders that Northwell be required to produce documents in response to the Subpoena only to the extent that doing so would not identify any of the 33 research subjects in the Article or research subjects in any other scholarly article authored by Dr. Moline, or provide information that could lead to identification of such subjects, and only to the extent that the Subpoena is otherwise non-objectionable;

- Expressly allows Northwell to redact otherwise responsive documents to protect the identities of the 33 research subjects in the Article or research subjects in any other scholarly article authored by Dr. Moline; and

- Strikes Attachment A, Request 6—which seeks the "[s]preadsheet in possession of Northwell identifying the 33 subjects of Exhibit 1, which lists the subjects' first and last names, brand(s) of talc they used, law firm representation, occupation(s), and date of diagnosis and/or date of birth"—in its entirety.

II. STANDARD OF REVIEW

The Federal Rules of Civil Procedure provide that, "[o]n timely motion, the court for the district where compliance is required ***must*** quash or modify a subpoena that . . . requires disclosure of privileged or other protected matter, if no exception or waiver applies . . . ." Fed. R. Civ. P. 45(d)(3)(A)(iii) (emphasis supplied). "The burden of persuasion in a motion to quash [or modify] a subpoena is borne by the movant." *Travelers Indem. Co. v. Metro. Life Ins. Co.*, 228 F.R.D. 111, 113 (D. Conn. 2005) (citations omitted); *see also Dove v. Atl. Capital Corp.*, 963 F.2d 15, 19 (2d

Cir. 1992) ("Where the discovery is relevant, the burden is upon the party seeking non-disclosure or a protective order to show good cause."). "The decision whether to quash or modify a subpoena is committed to the sound direction of the trial court." *Libaire v. Kaplan*, 760 F. Supp. 2d 288, 291 (E.D.N.Y. 2011).

III. ARGUMENT

Patient confidentiality and privacy are vital to medical research. The Court should modify the Subpoena to preserve the anonymity of the patients studied by Dr. Moline and referenced in her Article. The fundamental interests in protecting patient privacy and preserving the integrity of human subject research outweigh AII's interest in discovering the identity of these patients. The identities of these patients, *who are not parties to this litigation*, have no probative value to any of the issues in this case. Accordingly, modifying the Subpoena will not prejudice AII.

A. Northwell Has Significant Interests in Protecting the Identity of Research Subjects in Northwell IRB-Approved Research.

Dr. Moline's Article was researched and published consistent with Northwell's IRB processes, as directed by The Common Rule. The Common Rule is well-established federal policy aimed at protecting the safety, privacy, and confidentiality of research subjects. It imposes a series of requirements on institutions engaging in human subject research, which is subject to regulation by applicable federal agencies, including the U.S. Department of Health and Human Services ("HHS"). *See* 45 C.F.R. § 46.101. Institutions like Northwell that are engaged in human subject research are required to follow the policies and processes set forth within The Common Rule as part of the terms of the research institution's Federalwide Assurance established with the Office of Human Research Protections ("OHRP"), an office within HHS. *See* 45 C.F.R. § 46.103(a).

Although Dr. Moline did not have direct person-to-person contact with all patients in researching the Article, her analysis of identifiable medical records in preparing her research

findings qualifies as human subject research for purposes of The Common Rule. *See* 45 C.F.R. § 46.102 (defining human subject to include research in which a researcher obtains, uses, studies, or analyzes identifiable private information, such as a medical record). Accordingly, to conform to The Common Rule, Northwell's IRB required Dr. Moline to submit a research proposal demonstrating, among other requirements, that there were adequate protections in place to protect the privacy of the research subjects and to maintain the confidentiality of the patients' health data. 45 C.F.R. § 46.111. As discussed, Dr. Moline did just that, representing in her IRB application that: (1) she took confidentiality seriously and would take extensive measures to protect the participants' identities; (2) no patient identifiers would be included in research-related summaries; (3) all PHI included in her review and the Article would be de-identified; and (4) the PHI would be stored in Northwell's secure database. Huff Aff., Ex. F (Moline Aff. at ¶ 16). Further, in approving Dr. Moline's research proposal through the IRB informed consent waiver, the IRB had to establish that her proposal presented "no more than minimal risk of harm" to the research subjects, including a minimal risk of harm resulting from a breach of confidentiality. 45 C.F.R. § 46.117.

The IRB review process involves a balancing of the risk that research subjects may be harmed by unexpected or inadvertent release of their information, with the benefits that the research may provide to the public. As such, both Northwell and Dr. Moline have significant interests in protecting the anonymity of the research subjects. If researchers and research institutions that are non-parties to litigation are required to disclose the identities of anonymous research subjects, there would be a chilling effect on the IRB process and the medical community, including the potential for impeding the development of life-saving medical breakthroughs. Such disclosure requirements would require IRBs to reassess the risks and benefits associated with all

research proposals in light of the newly expanded risks to research subject confidentiality that such court orders would represent. And potential research subjects might well be disinclined to consent to participating in research at all. The fact that a litigant might be interested in discovering the identities of research subjects does not ameliorate this concern, nor does it change the representations Dr. Moline made to Northwell's IRB, or Northwell's IRB's obligations under The Common Rule. This is particularly true here, where the research subjects' identities are not central to any issue in this case.

In light of these concerns common throughout the medical research community, courts regularly protect the confidentiality of the research process, affording special discovery protections to research scholars and their research publications. *See, e.g., In re American Tobacco Co.*, 880 F.2d 1520 (2d Cir. 1989) (affirming the district court's protective order allowing non-party recipients of subpoenas to redact the names and other identifying information of participants in research studies and enjoining defendants from determining the identities of research participants from the information provided); *Cusumano v. Microsoft Corp.*, 162 F.3d 708 (1st Cir. 1998) (holding First Amendment considerations justify protecting academics engaged in scholarly research so as to prevent a chilling effect on the ability of researchers to gather and disseminate information); *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 249 F.R.D. 8, 13-14 (D. Mass. 2008) (finding chilling effects would occur if the identity of anonymous peer reviewers were required to be disclosed in product liability discovery). In *Cusumano*, the court noted the particular First Amendment harm to the free flow of information—essential to the research process—when researchers are ordered to violate their assurances of confidentiality. *Cusumano*, 162 F.3d at 716-717.

Courts have long recognized that this confidentiality is often "essential to the ability of researchers to obtain data." *Andrews v. Eli Lilly & Co., Inc.*, 97 F.R.D. 494, 499 (N.D. Ill. 1983), *vacated on other grounds, Deitchman v. E.R. Squibb & Sons, Inc.*, 740 F.2d 556 (7th Cir. 1984) (citing *Richards of Rockford, Inc. v. Pacific Gas & Electric Co.*, 71 F.R.D. 388, 390 (N.D. Cal. 1976); *Lampshire v. Proctor & Gamble Co.*, 94 F.R.D. 58 (N.D. Ga. 1982)). Indeed, as referenced above, even in related cases involving AII as a defendant, courts have protected the anonymity of research subjects except where they were parties to the litigation. *See Bell v. Am. Int'l Indus.*, No. 1:17-cv-00111 (M.D.N.C.); *Johnson/Lashley v. Am. Int'l Indus.*, Nos. MID-L-006651-16ASL and MID-L-007336-16AS (N.J. Super. Ct. Law Div.); *Fisher v. Am. Int'l Indus.*, No. 19070087 (Pa. D.&C.).

"The issue of confidentiality . . . [is] not an insurmountable one. . . . When a court is confronted with a motion to quash [an overbroad] subpoena, its duty is not to deny any discovery, but to reduce the demand to what is reasonable, considering the discoverer's needs and the discoveree's problems." *Deitchman*, 740 F.2d at 560. Recognizing this fact, Northwell does not seek to quash AII's Subpoena. Instead, it is seeking to modify the Subpoena in a fashion tailored to protect its legitimate interest in protecting research subjects' confidentiality (and, to that end, is making a good faith, contemporaneous production of documents in response to the Subpoena). Protecting the free flow of information to research partners not only benefits Northwell, but also serves a compelling societal interest that is jeopardized when confidentiality is breached. *See In re American Tobacco Co.*, 880 F.2d 1520; *Cusumano*, 162 F.3d at 708; *Andrews*, 97 F.R.D. at 499; *Richards of Rockford, Inc.*, 71 F.R.D. at 390; *Lampshire*, 94 F.R.D. at 58; *see also Farnsworth v. Procter & Gamble Co.,* 758 F.2d 1545, 1547 (11th Cir. 1985) (holding that the plaintiff's "interests in keeping its study participants' names confidential outweigh the discovery interests of [the

defendant]," in part, because "the ability to conduct probing scientific and social research supported by a population willing to submit to in-depth questioning" could be "seriously damage[d]" given "an expectation, not unjustified, that when highly personal and potentially embarrassing information is given for the sake of medical research, it will remain private.").

It also bears mentioning that Northwell's IRB expressly conditioned its approval of Dr. Moline's research on compliance with HIPAA. Huff Aff., Ex. F (Moline Aff. at ¶ 20). HIPAA provides a standalone basis for preserving the anonymity of the research subjects. *See* 45 C.F.R. § 160.103 (defining "protected heath information" as "individually identifiable health information," which in turn is defined as "information that is a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.").

B. Modifying the Subpoena in the Manner Sought by Northwell Will Not Prejudice AII.

Balanced against Northwell's interests, the Court must consider AII's need for the information sought. The modification of the Subpoena that Northwell seeks would not prevent AII from subpoenaing Dr. Moline to testify or produce documents. Nor would the modification limit AII from attempting to impeach Dr. Moline. This modification will not limit AII's counsel from questioning Dr. Moline about the background, methods, or analysis conducted by Dr. Moline in preparing her expert report. In fact, AII had the opportunity to question Dr. Moline on these topics during the course of her two-day deposition. In short, the modification sought by Northwell

will not prejudice or delay Defendant AII in any way. Instead, Northwell only seeks to protect the identities of *all* of the subjects of Dr. Moline's research pursuant to the federal standards imposed on IRBs and under HIPAA.

IV. CONCLUSION

For the foregoing reasons, Northwell respectfully requests that the Court grant its Motion, modify the Subpoena as Northwell requests, and enjoin AII from compelling Northwell to identify any research subjects or produce documentation from which the identities of research subjects can be ascertained.

This the 4th day of November, 2022.

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